SEP 2 4 2001

K012989

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461

XII. SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Breathable Surgical Gowns

Manufacturer:	Allegiance Healthcare Corporation One Butterfield Trail El Paso, Texas 79906
Regulatory Affairs Contact:	Sharon Robbins 1500 Waukegan Road MPWM McGaw Park, IL 60085
Telephone:	(847) 785-3311
Date Summary Prepared:	August, 2001
Common Name:	Convertors®Breathable Surgical Gowns
Classification:	Class II per 21CFR § 878.4040
Predicate Device:	Convertors® Breathable Surgical Gowns.
Description:	The gowns are comprised of a composite fabric of nonwoven fabric, monolithic breathable impervious film and nonwoven fabric.

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XII. SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Breathable Surgical Gowns

Intended Use:	Surgical apparel are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material.
Substantial Equivalence:	The Convertors® gowns are substantially equivalent to the Convertors® Breathable gowns in that: - the intended use is the same - the performance attributes are similar
Summary of testing:	All materials used in the fabrication of this Convertors®Breathable Gowns were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 " Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, sensitization, and irritation/ intracutaneous reactivity. These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2001

Ms. Sharon Robbins
Regulatory Affairs Manager
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K012984
Trade/Device Name: Breathable Impervious Gowns
Regulation Number: 878.4040
Regulation Name: Surgical Gowns
Regulatory Class: II
Product Code: FYA
Dated: September 4, 2001
Received: September 6, 2001

Dear Ms. Robbins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance

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510(k) Number (if known): Unknown (K012984)

Device Name: Convertors®Breathable Surgical Gowns

Indications For Use: The Convertors®Breathable Surgical Gowns are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K012984